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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,431	02/24/2004	Richard S. Sanders	GUID.048US01 (01-158)	8603

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EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT	PAPER NUMBER
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3766

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09/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/785,431	Applicant(s) SANDERS, RICHARD S.	
	Examiner DEBORAH MALAMUD	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 8-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner acknowledges the response received 21 April 2008. Claims 8-62 are withdrawn; claims 1-7 are pending.

Response to Arguments

2. Applicant's arguments filed 21 April 2008 have been fully considered but they are not persuasive. The Applicant argues (page 14, "Remarks") "the device of Hafelfinger delivers stimulation in both the unipolar and bipolar configurations. Hafelfinger does not disclose that stimulation circuitry is disabled in either the unipolar or bipolar configurations. Rather, stimulation circuitry is used in both configurations to deliver cardiac therapy. (See, e.g., element 48B of Fig. 3). For at least this reason, the Applicant respectfully submits that Hafelfinger fails to teach a monitoring mode in which energy delivery circuitry is disabled, in the manner claimed." It is noted that the functional language and introductory statement of intended use of claim 1, have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Hafelfinger utilizes electrodes that are capable of both sensing and energy delivery as claimed by the applicant, Hafelfinger is therefore capable of being used in a system that switches modes from monitoring and delivering, while the other mode is disabled. In addition nothing prevents Hafelfinger's system from being used in this manner. Therefore, they are capable of the mode switching use as described in the claim. The Applicant has not described, in the claims or in the arguments, how structurally Hafelfinger differs from the claimed invention.

3. The rejection of the claims is therefore maintained.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-2, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hafelfinger et al (U.S. 5,003,975). Hafelfinger discloses (col. 4, lines 1-41; Figs. 1, 1a) “an implantable pacemaker that has electrode configuration programming capabilities, as well as, unipolar/bipolar lead interchangeability (meaning that either unipolar or bipolar operation may be programmed, and either unipolar or bipolar leads may be inserted into the pacemaker connector block). The present invention utilizes load recognition (i.e., the load impedance presented by the lead/tissue interface during a stimulation pulse) to determine the integrity of the implanted leads and to automatically change the electrode configuration to an available and operative configuration.” The examiner considers this to be an implantable housing; a first electrode coupled to the housing and a second electrode; monitoring circuitry coupled to the first and second electrodes; and energy delivery circuitry coupled to the first and second electrodes. The device includes a “special monitoring circuit within the pacemaker that performs a lead impedance measurement whenever the operating configuration of the pacemaker is programmably changed, e.g., from bipolar to unipolar or vice versa. From this measurement, a determination is made as to whether the correct impedance is present for the existing operating configuration. If the expected impedance is not measured,

then a different configuration measurement is made according to a predefined sequence until a correct impedance value is measured. The occurrence of a correct measurement is then used to set the pacemaker configuration accordingly.” In other words, if a unipolar lead is sensed as connected to the device, the device is programmed to disable the energy delivery circuitry used in a bipolar lead. Therefore, the examiner considers Hafelfinger to disclose a lead interface coupled to the housing; and a controller coupled to the lead interface, monitoring circuitry, and energy delivery circuitry, the controller transitioning operation of the device from the monitoring mode, in which the energy delivery circuitry (used for a bipolar lead) is disabled, to the energy delivery mode, in which the energy delivery mode, in which the energy delivery circuitry is enabled, at least in part in response to coupling the cardiac lead to the lead interface (since coupling the lead triggers the lead impedance sensing that determines the mode to be used by the device).

6. Regarding claim 2, Hafelfinger discloses (col. 7, lines 18-22; Fig. 2) a "sensing detector (60) is coupled to the terminal (46) to respond to sensed heart activity." The examiner considers this to be detection circuitry provided in the housing and coupled to the first and second electrodes.

7. Regarding claims 5 and 7, Hafelfinger discloses, (col. 7, lines 46-52; Fig. 3) "A configuration switch 80 is shown connected between pairs of leads (12 and 14) via connectors (82A, 82B) and the pacing stimulation and sense stage (40B). Also shown is the connection to the case (31). In conventional fashion, a control microprocessor (84) or equivalent, is coupled to control the pacer stimulation and sense stage and the

configuration switch.” The examiner considers this to be a mode switch coupled to the controller; and a receiver coupled to the controller.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being obvious over Hafelfinger et al (U.S. 5,003,975) in view of Duggan (U.S. 5,318,593). Hafelfinger discloses the claimed invention except for a memory provided in the housing and coupled to the detection circuitry. Duggan however discloses (col. 7, lines 51-67; Figure 1) a “pacemaker (12) includes a body tissue and fluid resistant casing (13), a first lead (17) coupled to and attached by an electrode to the heart's atrium (40), and a second lead (19) coupled to and attached by an electrode to the patient's ventricle (42). Further, there is shown an external transmitter (10) coupled by a lead (15) to a coil or antenna (16) disposed externally of the patient's body (14), for transmitting RF coupled signals to the internally implanted pacemaker. Further, there is shown a monitor (63) coupled to the transmitter by a lead (59). As will be explained in detail, the transmitter (10) may be actuated to send signals via the lead (15) and the coil (16), to the internally implanted pacemaker (12), whereby its mode of operation may be changed from one mode to another selected mode; thus, the physician can control the type of pacing imposed upon the patient's heart in accordance with the patient's altered condition.” Duggan further discloses (col. 27, lines 8-24) “the leads could be coupled to heart

tissue, other tissue or transducers, to sense the patient's EKG, pulse rate, pulse width, the time of depolarization between the atrium and ventricle, etc. The time of transmission of a depolarization signal is considered to be indicative of the heart's condition and a window is established by a sensing program in accordance with a normal transmission time. If the received signal is outside the limits of such a window, an indication thereof is transmitted externally of the pacemaker. In a data gathering mode, it is contemplated that the latches associated with the associated leads to the heart sites, tissue sites, or transducers are coupled one at a time, by selectively closing the corresponding select switch (330), whereby that data is sent by the receiver (341) to an external monitoring device." Duggan and Hafelfinger both disclose systems for sensing cardiac activity and controlling pacemaker functions. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hafelfinger's implantable mode switch device with Duggan's implantable memory in order to store sensed signals for further diagnosis and study.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hafelfinger et al (U.S. 5,003,975) in view of Ideker et al (U.S. 6,205,357). Hafelfinger discloses the claimed invention except for a programmable filter coupled to the detection circuitry. Ideker however discloses (col. 7, lines 14-20) "electrodes shown in the positions illustrated panel 3A are, as shown in panel 3B, operatively connected to differential amplifiers (42, 42a, 42b, 42c), in turn connected to bandpass filters (44, 44a, 44b, 44c) and sensed event detector circuitry (46, 46a, 46b, 46c), contained in the ICD

(40). Amplification and bandpass filtering are followed by sensed event detection.”

Hafelfinger and Ideker both disclose devices for switching between sensing and stimulating modes. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hafelfinger's mode-switching and therapy-disabling system with Ideker's programmable filter in order to eliminate any noise from the sensed signal and prevent a misdiagnosis.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DEBORAH MALAMUD** whose telephone number is (571)272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Deborah L. Malamud/
Examiner, Art Unit 3766